IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Jenny LOUIE-HELM et al.

Serial No.: 10/014,750

Filing Date: October 25, 2001

Confirmation No.: 1055

Group Art Unit: 1618

Examiner: Blessing M. Fubara

Title: FORMATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE FORM USING IN VITRO DISINTEGRATION TEST DATA

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

A PTO-1449 form listing the references accompanies this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,910,021	3/20/90	Davis et al.
5,830,576	11/3/98	Mehra et al.
6,068,859	5/30/00	Curatolo et al.
6,562,375	5/13/03	Sako et al.
2003/0133985 A1	7/17/03	Louie-Helm et al.
2003/0152622 A1	8/14/03	Louie-Helm et al.
2004/0156899 A1	8/12/04	Louie-Helm et al.
2004/0185105 A1	9/23/04	Berner et al.

NONPATENT DOCUMENTS
BLOEM et al., "A controlled trial of a slow-release form of furosemide in hypertension," Curr. Ther. Res. (1981) 29:577-583.
BOLES PONTO et al., "Furosemide (frusemide): a pharmacokinetic/pharmacodynamic review, (Parts I and II), Clin. Pharmacokinetics (1990) 18:381-471.

NONPATENT DOCUMENTS
CONTE et al., "Modulation of the dissolution profiles from Geomatrix® multi-layer tablets containing drugs of different solubility," Biomater. (1996) 17:889-896.
GABR et al., "Formulation and evaluation of buffered floating furosemide delivery systems," S.T.P. Pharma Sci. (2000) 10:181-186.
GUSLER, et al., "Pharmacokinetics of metformin gastric-retentive tablets in healthy volunteers," J. Clin. Pharmacol. (2001) 41:655-661.
HUBER et al., "Utilization of hydrophilic gums for the control of drug release from tablet formulations. I. Disintegration and dissolution behavior," J. Pharmac. Sci. (1966) 55:974-976.
IANNUCCELLI et al., "PVP solid dispersions for the controlled release of furosemide from a floating multiple-dose unit system," Drug Dev. Indus. Pharm. (2000) 26:595-603.
KANIWA et al., "The bioavailability of flufenamic acid and its dissolution rate from capsules," Intl. J. Clin. Pharmacol., Ther. Toxicol. (1983) 21:56-63.
KORSMEYER et al., "Mechanisms of solute release from porous hydrophilic polymers," Intl. J. Pharmac. (1983) 15:25-35.
MENON et al., "Development and evaluation of a monolithic floating dosage form for furosemide," J. Pharmac. Sci. (1994) 83:239-245.
UCHINO et al., "Clinical pharmacokinetics and diuretic effect of furosemide in plain tablet and retard capsule with normal subjects and cirrhotic patients," J. Pharm. Dyn. (1983) 6:684-691.
WAKELKAMP et al., "The influence of frusemide formulation on diuretic effect and efficiency," J. Clin. Pharmacol. (1999) 48:361-366.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

This Information Disclosure Statement is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in 37 CFR § 1.491 in an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but *before* the mailing date of either a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, whichever occurs first. As such, enclosed is a check for $180.00 for payment of the fee set forth in 37 CFR § 1.17(p) for submission of an Information Disclosure Statement under 37 CFR § 1.97(c).

Respectfully submitted,

By: 

Leigh H. Firestone
Registration No. 36,831

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F:\Document\3100\0003\2nd Supp IDS.DOC

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/014,750
Filing Date	October 25, 2001
First Named Inventor	Jenny LOUIE-HELM
Art Unit	1618
Examiner Name	Blessing M. Fubara
Attorney Docket Number	3100-0003

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	EE	4,910,021	3/20/90	Davis et al.			
	EF	5,830,576	11/3/98	Mehra et al.			
	EG	6,068,859	5/30/00	Curatolo et al.			
	EH	6,562,375	5/13/03	Sako et al.			
	EI	2003/0133985 A1	7/17/03	Louie-Helm et al.			
	EJ	2003/0152622 A1	8/14/03	Louie-Helm et al.			
	EK	2004/0156899 A1	8/12/04	Louie-Helm et al.			
	EL	2004/0185105 A1	9/23/04	Berner et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	EM	BLOEM et al., "A controlled trial of a slow-release form of furosemide in hypertension," Curr. Ther. Res. (1981) 29:577-583.	
	EN	BOLES PONTO et al., "Furosemide (frusemide): a pharmacokinetic/pharmacodynamic review," (Parts I and II), Clin. Pharmacokinetics (1990) 18:381-471.	
	EO	CONTE et al., "Modulation of the dissolution profiles from Geomatrix® multi-layer tablets containing drugs of different solubility," Biomater. (1996) 17:889-896.	
	EP	GABR et al., "Formulation and evaluation of buffered floating furosemide delivery systems," S.T.P. Pharma Sci. (2000) 10:181-186.	
	EQ	GUSLER, et al., "Pharmacokinetics of metformin gastric-retentive tablets in healthy volunteers," J. Clin. Pharmacol. (2001) 41:655-661.	
	ER	HUBER et al., "Utilization of hydrophilic gums for the control of drug release from tablet formulations. I. Disintegration and dissolution behavior," J. Pharmac. Sci. (1966) 55:974-976.	
	ES	IANNUCCELLI et al., "PVP solid dispersions for the controlled release of furosemide from a floating multiple-dose unit system," Drug Dev. Indus. Pharm. (2000) 26:595-603.	
	ET	KANIWA et al., "The bioavailability of flufenamic acid and its dissolution rate from capsules," Intl. J. Clin. Pharmacol., Ther. Toxicol. (1983) 21:56-63.	
	EU	KORSMEYER et al., "Mechanisms of solute release from porous hydrophilic polymers," Intl. J. Pharmac. (1983) 15:25-35.	
	EV	MENON et al., "Development and evaluation of a monolithic floating dosage form for furosemide," J. Pharmac. Sci. (1994) 83:239-245.	
	EW	UCHINO et al., "Clinical pharmacokinetics and diuretic effect of furosemide in plain tablet and retard capsule with normal subjects and cirrhotic patients," J. Pharm. Dyn. (1983) 6:684-691.	
	EX	WAKELKAMP et al., "The influence of frusemide formulation on diuretic effect and efficiency," J. Clin. Pharmacol. (1999) 48:361-366.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FEE TRANSMITTAL for FY 2005

Effective 10/01/03. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	$205.00

Complete if Known	
Application Number	10/014,750
Filing Date	October 25, 2001
First Named Inventor	Jenny Louie-Helm
Examiner Name	Blessing M. Fubara
Group Art Unit	1618
Attorney Docket No.	3100-0003

METHOD OF PAYMENT *(check all that apply)*

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account No.	18-0580
Deposit Account Name	Reed IP Law Group

The Commissioner is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☒ Charge any underpayment or credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING, SEARCH AND EXAMINATION FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	790	2001	395	Utility filing fee *(filed on or before 12/8/04)*	
1011	300	2011	150	Utility filing fee *(filed after 12/8/04)*	
1111	500	2111	250	Search Fee	
1311	200	2311	100	Examination Fee	
1081	250	2081	125	For each additional 50 sheets exceeding 100	

SUBTOTAL (1) $

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims	53	- 52** =	1	x	$25	=	$25
Independent Claims	4	- 4** =	0	x		=	
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	50	2202	25	Claim in excess of 20
1201	200	2201	100	Independent claims in excess of 3
1203	360	2203	180	Multiple dependent claim, if not paid
1204	200	2204	100	** Reissue independent claims over original patent
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) $25

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1,020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1,080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1,000	2403	500	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	500	2452	250	Petition to revive – unavoidable	
1453	1,500	2453	750	Petition to revive – unintentional	
1501	1,400	2501	700	Utility issue fee (or reissue)	
1502	800	2502	400	Design issue fee	
1503	1,100	2503	550	Plant issue fee	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	$180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
1814	130	2814	65.00	Statutory Disclaimer	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** $180.00

SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Leigh H. Firestone	*Registration No. (Attorney/Agent)*	36,831	*Telephone*	(650) 251-7700
Signature	Leigh H. Firestone			*Date*	December 27, 2005